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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/950,016	09/10/2001	Janet A. Warrington	03848-00093	9580

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EXAMINER

JOHANNSEN, DIANA B

ART UNIT	PAPER NUMBER
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1634

DATE MAILED: 09/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/950,016	<b>Applicant(s)</b> WARRINGTON ET AL.	
	<b>Examiner</b> Diana B. Johannsen	<b>Art Unit</b> 1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 07 June 2005.  
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.  
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1,2,7-14,18-25 and 37 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.  
6) ☒ Claim(s) 1,2,7-14,18-25 and 37 is/are rejected.  
7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.  
8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.  
10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

509

### **FINAL REJECTION**

1. This action is in response to the Amendment and Response filed June 7, 2005. Claims 1-2, 7, and 22 have been amended. Claims 1-2, 7-14, 18-25 and 37 are now pending and under consideration. The amendments and arguments have been thoroughly reviewed, but are not persuasive for the reasons that follow. Any rejections not reiterated in this action have been withdrawn as being obviated by the amendment of the claims. **This action is FINAL.**

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

#### ***Claim Rejections - 35 USC § 112, first paragraph – written description***

#### **THE FOLLOWING ARE NEW GROUNDS OF REJECTION NECESSITATED BY APPLICANTS AMENDMENTS TO THE CLAIMS:**

3. Claims 1-2, 7-14, 18-25 and 37 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Specifically, while the claims refer to GenBank Accession No. U67963, the specification does not actually recite the sequence that corresponded to Accession No. U67963 at the time the instant invention was made. As database Accession entries are not fixed, but rather changeable over time, the recitation of this Accession No. in the claims does not convey to one of skill in the art the sequence actually possessed by Applicant at the time the

Art Unit: 1634

invention was made (the knowledge of which is required to practice the claimed invention – see also the discussion below in paragraph 4). As the sequence of the molecule employed by Applicant is not disclosed, the claims fail to comply with the written description requirement. It is further noted that as the GenBank Accession No. was not incorporated into the application by reference, amendment of the specification to add the sequence corresponding to Accession No. U67963 at the time the invention was made would constitute the addition of new matter.

***Claim Rejections - 35 USC § 112, first paragraph – enablement***

4. Claims 1-2, 7-14, 18-25, and 37 are rejected under 35 U.S.C. 112, first paragraph, because the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with the claims, for reasons set forth below and in the Office action of January 11, 2005. **It is noted that Applicants' amendment of the claims to recite GenBank Accession No. U67963 necessitated the new grounds of rejection included herein.**

It is first noted that **Applicant's arguments have overcome the instant rejection in part.** Specifically, with regard to monitoring the progression of cancer, Applicant's arguments that the claims do not require one to ascertain tumor stage, and that progression may be monitored by assaying for the spread of cancer to other sites, by determining the effectiveness of therapy, etc., are persuasive, and are sufficient to overcome the instant rejection with regard to monitoring progression.

Art Unit: 1634

With regard to the molecule described in the claims as "lysophospholipase-like," the response traverses the rejection on the grounds that the addition to the claims of the recitation "having a GenBank accession Number of U67963" allows one of skill to obtain the sequence of the claimed gene and therefore enables the claimed invention.

However, this argument is not persuasive, and this amendment necessitates a new ground of rejection, for the following reasons. Each of the claims now includes and requires the knowledge of the sequence set forth in GenBank Accession No. U67963 at the time the invention was made. However, the specification does not recite the sequence that corresponded to Accession No. U67963 at that time. As the sequence is not provided in the specification, and as knowledge of it is required to practice the methods of the claims, one of skill in the art must look to the teachings of the prior art to determine the identity of the sequence of the claims. However, as database Accession entries are not fixed, but rather changeable over time, the knowledge of this Accession No. does not convey to one of skill in the art the sequence actually possessed and employed by Applicant at the time the invention was made. Only Applicant is aware of the actual version of the sequence employed in, e.g., practicing the examples set forth in the specification. Thus, as neither the specification nor the prior art provide the sequence of the molecule actually employed by Applicant, it would require undue experimentation for one of skill in the art to use the claimed invention. Specifically, as no amount of experimentation would be sufficient to allow one of skill to ascertain what version of Accession No. U67963 was actually employed by Applicant, and as such knowledge is necessary in order for one of skill to practice the invention of the claims

Art Unit: 1634

with respect to "lysophospholipase-like having a GenBank Accession Number of U67963," the quantity of experimentation required to use the claimed invention is clearly undue.

***Claim Rejections - 35 USC § 112, second paragraph***

**THE FOLLOWING ARE NEW GROUNDS OF REJECTION NECESSITATED BY APPLICANTS AMENDMENTS TO THE CLAIMS:**

5. Claims 1-2, 7-14, 18-25 and 37 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-2, 7-14, 18-25 and 37 are indefinite over the recitation of the limitation "having a GenBank Accession Number of U67963" in claims 1, 2, 7, and 22. It is noted that the information associated with GenBank Accession numbers is periodically modified and updated. Accordingly, the recitation of such an Accession number in the claims renders them vague and indefinite, as the Accession number does not provide a clear and definite structural description of the molecule of the claims.

***Use of Trademarks***

6. The use of the trademark GENBANK is again noted in this application (see amendments to claims 1-2, 7 and 22). It should be capitalized wherever it appears.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner that might adversely affect their validity as trademarks.

***Conclusion***

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Diana B. Johannsen whose telephone number is 571/272-0744. The examiner can normally be reached on Monday-Friday, 7:30 am-4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached at 571/272-0745. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1634

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read "Diana B. Johannsen", with a long horizontal flourish extending to the right.

Diana B. Johannsen  
Primary Examiner  
Art Unit 1634  
September 6, 2005